

OCT 16 2002

K022327 1/2

**Attachment 5
510(k) Summary Statement for the
Lumenis Novus Spectra Laser System**

General Information:

Submitter: Lumenis
2400 Condensa Street
Santa Clara, California, U. S. A.
95051-0901

Contact Person: Karen Baker

Summary Preparation Date: October 10, 2002

Names:

Device Names: Novus Spectra Laser System

Primary Classification Name: 79 GEX, Laser Instrument, Surgical Powered

Predicate Devices:

Elite Solid State Green Diode Pumped 532nm
Elite Ultra Solid State Green Diode Pumped 532nm
Corium 200 Solid State Green Diode Pumped 532nm
Corium 400 Solid State Green Diode Pumped 532nm

Rationale for Substantial Equivalence:

The Novus Spectra Laser System has the same indications for use as the Elite family of lasers and the Corium series of lasers. They have similar functional elements such as treatment wavelengths, pulse rates, treatment power, spot size and cooling system. Control systems such as the door interlock, and the safety systems and displays are constantly monitored in these systems for user intervention during a procedure or maintenance.

Description of Submitted Device:

The Novus Spectra solid state, frequency-doubled, green Nd:YAG surgical laser system is an instrument used in the photothermolysis (photocoagulation) of soft tissue at an emission wavelength of 532nm.

Compatible delivery devices include: slit lamps, slit lamp adapters/attachments, laser indirect ophthalmoscopes (LIO), microfilters, collimated handpieces with spot sizes ranging from 200-1200microns, fibers and endocular and endotoo probes.

Indications for Use:

Ophthalmic Applications; Ear, Nose and Throat Applications; Dentistry; and Dermatologic Applications. A complete list is contained in the *Indications for Use Statement*.

Technological Characteristics and Substantial Equivalence

The Novus Spectra Laser System, the Elite family of lasers, and the Corium series deliver the same frequency-doubled Nd:YAG wavelength. Both deliver a 532nm wavelength of similar power and pulses having similar duration in single and repeat modes.

The Novus Spectra Laser System is identical to the Elite family of lasers, and the Corium series in terms of its intended uses and functionality. The Novus Spectra improves on the industry-standard digital operating environment present in the Elite to manage energy output, pulse duration and other functional aspects. A digital "closed loop" control system in the Novus Spectra replaces the analog "closed loop" control system in the Elite and Corium. In addition the digital environment improves the overall safety of the system through improved and more rigorously controlled hazard mitigation hardware

Conclusion

The Novus Spectra Laser System is substantially equivalent to the Elite and Corium laser systems that are now in commercial distribution and have been successful in meeting the intended uses. The Novus Spectra has an improved hazard mitigation and risk management operating environment that reduces the level of concern regarding its uses per the Intended Uses document.

The Lumenis Novus Spectra shares the same intended use, indications for use, and similar technological characteristics as the predicate laser systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 16 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen Baker
Regulatory Consultant to Lumenis, Inc.
Lumenis, Inc.
2400 Condensa Street
Santa Clara, California 95051-0901

Re: K022327

Trade/Device Name: Novus Spectra Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: July 10, 2002
Received: July 18, 2002

Dear Ms. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

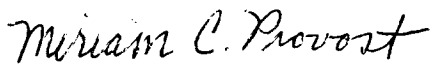
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Karen Baker

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2
Indications for Use Statement as Requested by FDA

510(K) Number (if Known): K022327

Device Name: Novus Spectra Laser System

Indications for Use:

Ophthalmology

Retinal Photocoagulation
Trabeculoplasty
Iridotomy
Diabetic retinopathy
Peripheral Iridectomy
Posterior and Anterior procedures
Senile macular degeneration

Ear, Nose and Throat (ENT)

Stapedectomy
Stapedotomy
Myringotomies
Lysis of Adhesions
Control of Bleeding
Removal of Acoustic Neuromas
Soft Tissue Adhesion in Micro/Macro Otologic Procedures

Dermatology

Pigmented lesions, including solar lentigines
Vascular lesions, including cherry hemangiomas and angiokeratomas
Extremities telangiectasias, including facial and leg telangiectasias
Cutaneous lesions
Flat warts
Dermatosis
Papulosa Nigra

Dentistry

- Frenectomy
- Treatment of Oral Mucous Cyst
- Treatment of Benign Vascular Lesions:
 - Capillary hemangioma
 - Hemorrhagic hereditary telangiectasia
 - Capillary/cavernous hemangiomas
 - Lymphangioma
 - AV malformation of the tongue
 - Hemangiolymphangiomas
- Photocoagulation of superficial vessels
- Vaporization of superficial blood or lymph containing vessels
- Treatment of superficial tongue lesions
- Tissue management and hemostasis for crown and bridge impressions
- Incision and drainage for abscess
- Gingivoplasty/ gingivectomy
 - Operative procedures
 - Crown and bridge, gingival reduction
 - Crown lengthening
- Hyperplasia (Drug, Irritation, Epulis,...)
- Hemostasis during dental procedures
- Operculectomy (Operculotomy)
- Excisional biopsy
- Free Gingival Graft (Adjunct):
 - Hemostasis of donor site
 - Hemostasis of graft site
- Vestibuloplasty
- Soften Gutta Percha
- Treatment of canker sores, herpetic lesions, and aphthous ulcers
- Laser-assisted bleaching/whitening

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓
(Per 21 CFR 801.109)

OR
Miriam C. Probst Over-The-Counter Use: _____
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022327